# IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES INC., ET AL.,

Plaintiffs,

v.

C.A. No. 08-21-GMS-LPS

CONSOLIDATED

COBALT LABORATORIES INC., ET AL.,

Defendants.

## REPORT AND RECOMMENDATION

Plaintiffs in this patent infringement action are Merz Pharma GmbH & Co. KGaA, Merz Pharmaceuticals GmbH, Forest Laboratories, Inc., and Forest Laboratories Holdings, Ltd. (collectively, "Plaintiffs"). Plaintiffs hold all ownership interests in U.S. Patent No. 5,061,703 ("the '703 Patent"), entitled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia." Among the twenty-six defendants are Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid India"), Orchid Pharmaceuticals, Inc. ("Orchid Pharma"), and Orgenus Pharma, Inc. ("Orgenus").

Presently pending before the Court are motions to dismiss for lack of personal jurisdiction filed by Orchid India and Orgenus (hereinafter referred to together as "Defendants"). (Docket Item No. ("D.I.") 43; D.I. 87)<sup>1</sup> Defendants contend that they do not have sufficient contacts with Delaware to allow this Court to exercise jurisdiction over them. Plaintiffs disagree

<sup>&</sup>lt;sup>1</sup>Unless otherwise noted herein, all docket entries to which I refer may be found in the lead case, C.A. No. 08-21-GMS-LPS.

and oppose Defendants' motions. Plaintiffs also argue that if the Court finds a lack of personal jurisdiction with respect to Orchid India or Orgenus, then these actions against these Defendants should be transferred to the U.S. District Court for the District of New Jersey, where there is, undisputedly, jurisdiction. (D.I. 99; D.I. 153)

I find that there are insufficient contacts between Delaware and Orchid India or Orgenus and, therefore, that this Court lacks personal jurisdiction over these Defendants. However, I also find that dismissal would be inappropriate and, instead, that transfer is warranted. Accordingly, I recommend that Plaintiffs' motions to transfer be granted and that Defendants' motions to dismiss be denied as moot.<sup>2</sup>

#### **BACKGROUND**

#### A. The Plaintiffs

Plaintiff Merz Pharma GmbH & Co. KGaA is a German corporation with its principal place of business in Germany. (D.I. 1 ¶ 3) Plaintiff Merz Pharmaceuticals GmbH is also a German corporation with a principal place of business in Germany. (*Id.* at ¶ 4) The Merz entities are the sole assignees of the '703 Patent. (*Id.* at ¶ 27)

<sup>&</sup>lt;sup>2</sup>Pursuant to the March 20, 2008 and June 10, 2008 referral orders (C.A. No. 08-21-GMS-LPS D.I. 55; C.A. No. 08-291-GMS-LPS D.I. 13), as well as 28 U.S.C. § 636, my authority with respect to the case-dispositive motions to dismiss is limited to issuing a Report and Recommendation ("R&R"). There is a split of authority as to whether a motion to transfer is also case-dispositive. *Compare Oliver v. Third Wave Techs.*, *Inc.*, 2007 WL 2814598, at \*2 n.3 (D.N.J. Sept. 25, 2007) (magistrate judge issuing R&R concerning motion to transfer venue in patent case) *with Kendricks v. Hertz Corp.*, 2008 WL 3914135, at \*2 (D.V.I. Aug. 18, 2008) ("A motion to transfer venue is not a dispositive motion."); *Berg. v. Aetna Freight Lines*, 2008 WL 2779294, at \*1 n.1 (W.D. Pa. July 15, 2008) (same). Given the uncertainty on this point, as well as the parties' request for an R&R (D.I. 227; D.I. 228), I will treat all of the pending motions as case-dispositive and issue an R&R.

Plaintiff Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation with its principal place of business in New York. (*Id.* at ¶ 1) Plaintiff Forest Laboratories Holdings, Ltd. ("Forest Holdings"), a wholly-owned subsidiary of Forest Labs, is an Irish corporation with its principal place of business in Bermuda. (*Id.* at ¶ 2) The Forest entities are the exclusive licensees of the '703 Patent in the United States. (*Id.* at ¶ 28) Forest also holds New Drug Application ("NDA") No. 21-487 for Namenda brand memantine hydrochloride tablets. (*Id.*) The '703 Patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book," i.e., the *Approved Drug Products with Therapeutic Equivalence Evaluations*, for Namenda. (*Id.*) The Forest entities are the exclusive distributors of Namenda in the United States. (*Id.* at ¶ 29)

#### B. The Defendants

Defendant Orchid India is an Indian company with its principal place of business in India.

(Id. at ¶ 9) It is involved in the development and manufacture of active pharmaceutical ingredients and finished dosage forms, as well as drug discovery. (D.I. 44 at 4; D.I. 45 ¶ 2)

Defendant Orchid Pharma is a wholly-owned subsidiary of Orchid India. (D.I. 1 ¶ 8; D.I. 46 ¶ 2; D.I. 89 at 6) Orchid Pharma is a holding company incorporated in Delaware with a principal place of business in Delaware. (D.I. 1 ¶ 8; D.I. 44 at 5; D.I. 45 ¶ 4; D.I. 46 ¶¶ 2, 4; D.I. 89 at 3, 6) Orchid Pharma is essentially a shell corporation; the only action it has ever taken was to incorporate co-defendant Orgenus. (D.I. 100 at 23-26; D.I. 101 Ex. 2; D.I. 165 at 6, Ex.2; D.I. 226 (Transcript of Nov. 12, 2008 Hearing; hereinafter "Tr.") at 38, 48-50)<sup>3</sup>

<sup>&</sup>lt;sup>3</sup>Orchid Pharma has not moved to dismiss. However, Plaintiffs, in connection with their fallback request for transfer, have asked that, if jurisdiction is found to be lacking over Orchid India or Orgenus, its action against Orchid Pharma be dismissed. (See Tr. at 38-39.) For reasons

Defendant Orgenus, a wholly-owned subsidiary of Orchid Pharma, is a New Jersey corporation having its principal place of business in New Jersey. (D.I. 89 at 3, 5; D.I. 90 ¶¶ 2-3; C.A. No. 08-291 D.I. 1 ¶ 5) Orgenus is Orchid India's primary business contact for the United States and Canada. (D.I. 89 at 5; D.I. 90 ¶ 2)

Another entity, Orchid Healthcare, Ltd. ("Orchid Healthcare"), is a division of Orchid India. (D.I. 44 at 4; D.I. 45 ¶ 3) Orchid Healthcare is not a defendant.

# C. Defendants' ANDA

On October 16, 2007, Orchid India, through its Orchid Healthcare division, submitted Abbreviated New Drug Application ("ANDA") No. 90-044, seeking FDA approval to manufacture and distribute "generic" versions of memantine hydrochloride in the United States. (D.I. 1 ¶ 45; D.I. 45 ¶ 14; D.I. 46 ¶¶ 11-12; D.I. 89 at 5; D.I. 90 at 12-13; C.A. 08-291 D.I. 1 ¶ 16)<sup>4</sup> The ANDA had been prepared by Orchid India in India. (D.I. 44 at 5; D.I. 45 ¶ 15; D.I. 90 ¶ 14) The ANDA named Orgenus as Orchid India's U.S. regulatory agent. (D.I. 44 at 5; D.I. 45 ¶ 14; D.I. 46 ¶¶ 10-11 & Ex. A; D.I. 89 at 5; D.I. 90 ¶¶ 11-12) Orgenus was also responsible for the physical act of submitting the ANDA, having placed it in the mail to the FDA in Maryland from Orgenus' place of business in New Jersey. (D.I. 44 at 5; D.I. 46 ¶ 11; D.I. 89 at 5; D.I. 90 ¶ 12) Orchid Pharma did not participate in, contribute to, or otherwise aid in the preparation of ANDA No. 90-044 or in its submission to the FDA. (D.I. 44 at 5-6;

to be discussed in relation to the transfer motions, I recommend that Orchid Pharma be dismissed.

<sup>&</sup>lt;sup>4</sup>For a discussion of the Hatch-Waxman Act and the ANDA process, see Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 676-78 (1990).

D.I. 45 ¶ 16; D.I. 46 ¶ 8; D.I. 89 at 6; D.I. 90 ¶ 14)

## D. Defendants' Contacts With Delaware

Jurisdictional discovery is complete. From the record before me, it is clear – and undisputed – that neither Orchid India nor Orgenus has any offices, facilities, employees, telephone listings, bank accounts, or property in Delaware. Neither of them are registered to do business or licensed to sell drugs in Delaware. Nor do either of the Defendants solicit business here, sell products here, or derive substantial revenues from sales here. They do not engage in advertising directly to U.S. consumers, including in Delaware; have not commenced any legal actions or proceedings in Delaware; and have not been named as defendants in any Delaware actions. (D.I. 44 at 4-5; D.I. 45 ¶ 7, 9-11; D.I. 89 at 5-6; D.I. 90 ¶ 5-10)

Furthermore, Orchid India's employees do not make regular visits to Delaware.

(D.I. 45 ¶ 8) Nor does Orchid India sell products directly to retailers in the United States; instead, it partners with other companies who sell its products in this country. (D.I. 44 at 4-5; D.I. 45 ¶ 9) Likewise, Orgenus does not sell or distribute any products anywhere in the United States. (D.I. 89 at 5-6; D.I. 90 ¶¶ 6-7) Orgenus also does not contract with Orchid India's business partners in the United States. (D.I. 89 at 5-6; D.I. 90 ¶ 6)

Nonetheless, Plaintiffs assert there are multiple contacts between Defendants and Delaware that give rise to personal jurisdiction. The nature of these asserted contacts, and the record evidence relating to them, are described below.

#### 1. Purchases from Delaware companies

Orchid India often uses materials (e.g., excipients, packaging) in its generic products that are supplied by companies incorporated in or located in Delaware. (D.I. 152 at 13) If its memantine ANDA is approved, Orchid India will likely purchase resin for the containers from Chevron Phillips Chemical Company, the closure for the containers from Rexam Closures and Containers, and the liner for the closures from Selig Sealing Products, Inc. (*Id.*) All three of these are Delaware companies, although they are located outside of Delaware, in Texas, Indiana, and Illinois, respectively. (D.I. 133 at 15; D.I. 134 Ex. 7)

Relatedly, the component comprising the largest portion (81% by weight) of Orchid India's proposed generic tablets, microcrystalline cellulose ("MCC"), is manufactured by FMC BioPolymer, a company located in Delaware. (D.I. 152 at 13; Tr. at 43-44) However, invoices show that it was purchased by Orchid India from an Indian company – Signet Chemical Corporation – in India. (D.I. 133 at 7, 14-15; D.I. 134 Exs. 5, 8)

Also, Orchid India has entered into at least nine agreements (covering eight products) with Quest Pharmaceuticals Services ("Quest"), a Delaware corporation located in Newark, Delaware, giving Orchid India an ongoing relationship with a Delaware company located in Delaware. (D.I. 165 at 3-4 & Exs. 9-17) In particular, the record contains 46 invoices from Quest to Orchid India for analytic services provided over a period of three years. (Tr. at 47)

## 2. Distribution agreements with Delaware companies

"Orchid India also . . . has five or six separate distribution deals with Delaware companies for its ANDA products." (Tr. at 47; see also Tr. at 39; D.I. 100 at 10-12; D.I. 152 at

7-9; D.I. 165 at 3.) Relatedly, Orgenus has entered into at least five confidentiality agreements with Delaware entities that were either current or prospective distribution partners of Orchid India. (D.I. 152 at 12 & Exs. 15-19)

## 3. Clinical trials conducted by Delaware companies

Clinical trials – specifically, bioavailability and bioequivalence in vivo testing – relating to Orchid India's memantine ANDA were performed by a Delaware company, AAIPharma, Inc. (D.I. 152 at 13; see also D.I. 100 at 18-19; D.I. 102 Ex. 26) Orchid India submitted the results of these tests to the FDA as part of its ANDA. (*Id.*) The actual tests, however, were performed outside of Delaware, in North Carolina and Kansas. (D.I. 133 at 15-16; D.I. 134 Exs. 9, 10)

## 4. Visits to Delaware by sales representatives

Orchid India representatives came to Delaware to enter into an alliance with DuPont relating to safety standards. Specifically, four Orchid India representatives made a single visit to DuPont in Delaware. (D.I. 133 at 9; D.I. 134 Ex. 5; Tr. at 17) During this visit, the representatives did not conduct any business relating to Orchid India's memantine ANDA. (D.I. 133 at 9; D.I. 134 Ex. 5; Tr. at 17) Instead, their activities primarily consisted of visiting a DuPont work site and a museum. (D.I. 133 at 9; D.I. 134 Ex. 5)

## 5. Incorporation in Delaware of Orchid Pharma

In 2004, Orchid India incorporated its wholly-owned subsidiary, Orchid Pharma, in Delaware. (D.I. 100 at 9, 14) In turn, Orchid Pharma incorporated Organus in New Jersey.

(D.I. 100 at 23-26; D.I. 101 Ex. 2; D.I. 165 at 5; Tr. at 50)

Orchid Pharma is a holding company and, as Plaintiffs now recognize, a "shell." (Tr. at 38, 48-50) Orchid Pharma does not conduct any business activities and has no independent officers, directors, or employees; day-to-day management and operations are the responsibility of the Vice President for Business Development of Orgenus. (D.I. 100 at 22-23; D.I. 152 at 16-17) Orchid Pharma has no revenues or assets and depends on loans from Orchid India, which is also responsible for Orchid Pharma's liabilities. (D.I. 100 at 24; D.I. 152 at 17; D.I. 165 at 5) The only act Orchid Pharma has ever taken – incorporating Orgenus – was done for the benefit of Orchid India.

Nonetheless, Orchid Pharma is a stand-alone corporate entity, observing all proper corporate formalities. Orchid India, Orchid Pharma, and Orgenus have separate accounting functions and books, separate bank accounts, separate employees, and separate corporate identities. (D.I. 44 at 3, 6, 12-13; D.I. 45 ¶¶ 12-13; D.I. 46 ¶¶ 4-7; D.I. 89 at 3; D.I. 90 ¶ 4; D.I. 163 at 6-7) Orchid Pharma makes its own decisions through its own independent board. (D.I. 163 at 7) Orchid Pharma raised its operating capital through the issuance of stock; payments it received from Orchid India are recorded on its books as loans. (D.I. 163 at 7-8; D.I. 165 at 5; D.I. 188 at 5)

## 6. Relationship between Orchid Pharma and Orgenus

Organus was incorporated by Orchid Pharma and remains Orchid Pharma's wholly-owned subsidiary. (D.I. 89 at 3, 5; D.I. 90 ¶¶ 2-3; D.I. 100 at 23-26; D.I. 101 Ex. 2; D.I. 165 at 5; C.A. 08-291 D.I. 1 ¶ 5; Tr. at 50) But Orchid Pharma is not involved in the daily management of

Organus. (D.I. 163 Ex. 1) Organus makes it own strategic decisions and has no power to act or sign on behalf of Orchid Pharma. (*Id.*) The relationship between Organus and Orchid India is governed by Services Agreements between these two entities, to which Orchid Pharma is not a party. (D.I. 89 at 5; D.I. 90 ¶ 10; D.I. 100 at 15; D.I. 102 Ex. 16; D.I. 152 at 12; D.I. 163 Ex. 1; D.I. 165 at 5; D.I. 188 at 5)

# 7. Role as Orchid India's U.S. ANDA agent

Plaintiffs insist that Orchid Pharma has acted as Orchid India's agent for FDA filing purposes. (D.I. 100 at 9, 14) The only evidence they can cite, however, is an ambiguous statement in Orchid India's 2004 Annual Statement:

The US coordination work including acting as agent for filing of regulatory submissions with the US FDA was being carried out through a branch office in New Jersey, USA hitherto. In order to cater to the more demanding requirements of the US market, the Board felt that it would be more appropriate to have a separate entity formed in the US. Accordingly, your Company promoted Orchid Pharmaceuticals Inc. in Delaware state of USA as a 100% subsidiary company during the year under review.

(D.I. 63; D.I. 102 Ex. 6 at OCP00000368) While this statement suggests an intent to use Orchid Pharma as Orchid India's agent, there is no evidence that Orchid Pharma ever actually performed this function.

#### 8. Delaware choice of law provisions

Defendants' Services Agreements, to which the only parties are Orchid India and other Orchid entities, are governed by Delaware law; in particular, Orchid India and Orgenus chose Delaware law to govern disputes arising from their relationship. (D.I. 100 at 15;

D.I. 102 Ex. 16; D.I. 152 at 12) Orchid India and/or Orgenus are also parties to at least two other agreements with other companies that contain Delaware choice-of-law provisions.
(D.I. 100 at 15; D.I. 102 Ex. 15; D.I. 133 at 8; D.I. 152 at 12 & Exs. 20, 21)

#### 9. Intent to do business in Delaware

It is undisputed that Orchid India, in cooperation with others, markets and distributes generic pharmaceuticals throughout the United States. (D.I. 44 at 4-5; Tr. at 16) It is further conceded that if Orchid India's memantine ANDA is approved then Orchid India will seek to distribute its generic version throughout the country. (D.I. 100 at 12; D.I. 101 Ex. 2; Tr. at 16) There is no evidence that Orchid India has ever sought to exclude from its sales efforts Delaware or a region of the country containing Delaware. (Tr. at 16 (Defendants: "[T]here is nothing in the record that indicates that Orchid [India] has ever excluded any region of the United States . . . . "))

## E. Procedural Background

Plaintiffs filed their complaint against Orchid India and Orchid Pharma, among others, on January 10, 2008. (D.I. 1) On March 3, 2008, Orchid India filed its Motion to Dismiss for Lack of Personal Jurisdiction. (D.I. 43) On April 15, 2008, I ordered jurisdictional discovery. (D.I. 64)

After learning that Orchid India's agent in connection with the memantine ANDA was Orgenus, and not Orchid Pharma, Plaintiffs filed a separate action against Orgenus on May 16, 2008. (C.A. 08-291 D.I. 1) On June 2, 2008, Plaintiffs' two actions were consolidated for all purposes, with the original action (C.A. 08-21) being designated the lead case. (D.I. 76;

C.A. 08-291 D.I. 10)

Organus filed its Motion to Dismiss for Lack of Personal Jurisdiction on June 19, 2008.

(D.I. 87) Plaintiffs filed their responses to Orchid India's and Organus' motions, including Plaintiffs' contingent requests to transfer their claims, on June 27 and August 22, 2008, respectively. (D.I. 99; D.I. 153)

I held oral argument on all pending motions on November 12, 2008. (D.I. 226) After the filing of additional submissions ordered by the Court, briefing on these motions was completed on November 19, 2008. (D.I. 227; D.I. 228)

#### **LEGAL STANDARDS**

#### A. Motions To Dismiss - 12(b)(2)

Federal Rule of Civil Procedure 12(b)(2) directs the Court to dismiss a case when it lacks personal jurisdiction over the defendant. Determining the existence of personal jurisdiction requires a two-part analysis. First, the Court analyzes the long-arm statute of the state in which the Court is located. *See Intel Corp. v. Broadcom Corp.*, 167 F. Supp. 2d 692, 700 (D. Del. 2001). Next, the Court must determine whether exercising jurisdiction over the defendant in this state comports with the Due Process Clause of the Constitution. *See id.* Due Process is satisfied if the Court finds the existence of "minimum contacts" between the non-resident defendant and the forum state, "such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotation marks omitted). In undertaking the Due Process inquiry, the Court applies the law of the Federal Circuit.

Once a jurisdictional defense has been raised, the plaintiff bears the burden of establishing, by a preponderance of the evidence and with reasonable particularity, the existence of sufficient minimum contacts between the defendant and the forum to support jurisdiction. *See Provident Nat'l Bank v. California Fed. Sav. & Loan Ass'n*, 819 F.2d 434, 437 (3d Cir. 1987); *Time Share Vacation Club v. Atlantic Resorts, Ltd.*, 735 F.2d 61, 66 (3d Cir. 1984). To meet this burden, the plaintiff must produce "sworn affidavits or other competent evidence," since a Rule 12(b)(2) motion "requires resolution of factual issues outside the pleadings." *Time Share*, 735 F.2d at 67 n.9; *see also Philips Electronics North America Corp. v. Contec Corp.*, 2004 WL 503602, at \*3 (D. Del. Mar. 11, 2004) ("After discovery has begun, the plaintiff must sustain [its] burden by establishing jurisdictional facts through sworn affidavits or other competent evidence.").

#### B. Motions To Transfer

Under appropriate circumstances, transfer of a case from one federal court to another is authorized by 28 U.S.C. § 1406(a) and 28 U.S.C. § 1631. The burden of demonstrating the appropriateness of such a transfer rests with the moving party. *See Plum Tree, Inc. v. Stockment*, 488 F.2d 754, 756-57 (3d Cir. 1973); *ADE Corp. v. KLA-Tencor Corp.*, 138 F. Supp. 2d 565, 567 (D. Del. 2001).<sup>5</sup>

<sup>&</sup>lt;sup>5</sup>To the extent the caselaw addresses 28 U.S.C. §1404(a) (as opposed to §1406(a)), it should be noted that the Third Circuit has previously commented "we think [the] rationale [of § 1406(a)] applies equally to § 1404(a), for these are companion sections, remedial in nature, enacted at the same time, and both dealing with the expeditious transfer of an action from one district or division to another." *U.S. v. Berkowitz*, 328 F.2d 358, 359 (3d Cir. 1964).

## **DISCUSSION**

#### A. Delaware's Long-Arm Statute

Delaware's long-arm statute, 10 Del. C. § 3104(c), provides in pertinent part:

A Delaware court has personal jurisdiction over a non-resident defendant only when that non-resident defendant, either in person or through an agent:

- (1) Transacts any business or performs any character of work or service in the State;
- (2) Contracts to supply services or things in this State;
- (3) Causes tortious injury in the State by an act or omission in this State;
- (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State;
- (5) Has an interest in, uses or possesses real property in the State; or
- (6) Contracts to insure or act as surety for, or on, any person, property, risk, contract, obligation or agreement located, executed or to be performed within the State at the time the contract is made, unless the parties otherwise provide in writing.

Delaware's courts have construed Delaware's long-arm statute "liberally so as to provide jurisdiction to the maximum extent possible. In fact, the only limit placed on § 3104 is that it remain within the constraints of the Due Process Clause." *Boone v. Oy Partek*, 724 A.2d 1150, 1157 (Del. Super. Ct. 1997) (internal citations omitted), *aff'd*, 707 A.2d 765 (Del. Supr. 1998) (table); *see also Hercules, Inc. v. Leu Trust and Banking (Bahamas) Ltd.*, 611 A.2d 476, 480 (Del. 1992).

Plaintiffs assert that this Court has "general jurisdiction" over Orchid India and Orgenus

pursuant to subsection (c)(4) of Delaware's long-arm statute and "specific jurisdiction" pursuant to subsections (c)(1) and (c)(3). They further contend that this Court can exercise "dual jurisdiction" under a combination of subsections (c)(1) and (c)(4) and also that the long-arm statute is satisfied because Orchid Pharma – the Delaware corporation – is the "alter ego" or "agent" of Orchid India and Orgenus. Below I analyze, and reject, each of these contentions.

## 1. General Jurisdiction

Subsection (c)(4) of Delaware's long-arm statute confers "general" jurisdiction over a non-resident defendant. See, e.g., LaNuova D &B, S.p.A. v. Bowe Co., 513 A.2d 764, 768 (Del. Supr. 1986); Jeffreys v. Exten, 784 F. Supp. 146, 153 (D. Del. 1992). "[G]eneral' jurisdiction [is that jurisdiction] in which the defendant's contacts have no necessary relationship to the cause of action." Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1562 n.10 (Fed. Cir. 1994); see also Boone, 724 A.2d at 1155. For general jurisdiction to be present, a defendant must have continuous and systematic contacts with the forum state. See Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414-15 (1984). Neither Orchid India nor Orgenus have continuous and systematic contacts with Delaware.

As already noted above, neither Orchid India nor Orgenus have any offices, facilities, employees, telephone listings, bank accounts, or property in Delaware; neither are registered to do business or sell pharmaceuticals here; nor do they advertise, derive substantial revenues, or initiate litigation here. Plaintiffs' contention that Defendants, nonetheless, have continuous and

 $<sup>^6</sup>$ The parties agree that subsections (c)(2), (c)(5), and (c)(6) have no application to the facts of this case.

systematic contacts with Delaware rests largely on the fact that Orchid India incorporated its wholly-owned subsidiary, Orchid Pharma, in Delaware; and Orchid Pharma, in turn, incorporated Orgenus. But Orchid Pharma is a shell corporation; incorporating such an entity does not satisfy subsection (c)(4). *See Applied Biosystems Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1467 (D. Del. 1991) (holding that when a company has "done little more in Delaware than is necessary to comply with corporate formalities, this activity is insufficient to meet the terms of subsection (c)(4)." Likewise, nothing about Orchid Pharma's incorporation of Orgenus, nor the ongoing relationship between these two companies, makes for continuous and systematic contacts between Orgenus and Delaware.

The other "contacts" Plaintiffs identify between Defendants and Delaware are also inadequate, individually as well as collectively. Orchid India's purchases of analytic services from Quest, a Delaware company located in Delaware, as well as its agreements to have Delaware companies distribute its generic drugs, are inadequate to warrant a finding of general jurisdiction. *See, e.g., Helicopteros*, 466 U.S. at 418 ("[W]e hold that mere purchases, even if occurring at regular intervals, are not enough to warrant a State's assertion of in personam jurisdiction over a nonresident corporation in a cause of action not related to those purchase transactions."); *Glaxo, Inc. v. Genpharm Pharmas., Inc.*, 796 F. Supp. 872, 876 n.8 (E.D.N.C. 1992) (no jurisdiction found despite a contract for analytical services concerning a drug unrelated to the case); *Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 372, 375 (D. Del. 2002) (holding in ANDA case that two licenses to sell products in Delaware, direct sales to Delaware pharmacy, contract for sale and distribution of \$1.2 million of drug per month in Delaware, and substantial revenue generated in Delaware do not amount to significant contacts);

Monsanto Co. v. Syngenta Seeds, Inc., 443 F. Supp. 2d 636, 643-46 (D. Del. 2006) (holding that ownership of Delaware subsidiary, attending meeting in Delaware, final say over whether subsidiaries would market accused product, and overlap of some officers and directors were insufficient contacts). The same is true of Orchid India's purchase of excipients and packaging materials from Delaware companies and its payments to Delaware companies for clinical trials.

Likewise, while Orchid India chose Delaware law to govern its legal relationship with other companies, including Orgenus, Delaware courts have refused to base personal jurisdiction solely on the existence of such a choice of law provision, *see*, *e.g.*, *Intellimark*, *Inc. v. Rowe*, 2005 WL 2739500, at \* 2 (Del. Super. Ct. Oct. 24, 2005), even when the Delaware choice of law provision was in a contract related to the plaintiff's cause of action, *see Summit Investors II*, *L.P. v. Sechrist Indus.*, *Inc.*, 2002 WL 31260989, at \* 4 (Del. Ch. Ct. Sept. 20, 2002). Plaintiffs assert that Orgenus has facilitated several distribution agreements between Orchid India and numerous Delaware entities to distribute Orchid India's products throughout the United States, including Delaware. But if entering into such distribution agreements directly with a Delaware entity is not sufficient to establish general jurisdiction, then neither does facilitating such agreements. Finally, while Delaware sales of products other than that involved in the instant litigation might provide a basis for general jurisdiction, *see Eli Lilly and Co. v. Mayne Pharma (USA) Inc.*, 504 F. Supp. 2d 387, 393-95 (S.D. Ind. 2007), there is no evidence that either Orchid India nor Orgenus has derived substantial revenues from sales in Delaware.

In sum, the record does not demonstrate continuous and systematic contacts between Orchid India or Orgenus and Delaware. Plaintiffs have failed to meet their burden to establish general jurisdiction.

#### 2. Specific Jurisdiction

Subsections (c)(1) and (c)(3) of the Delaware long-arm statute confer "specific" jurisdiction over a non-resident defendant. *See, e.g.,LaNuova,* 513 A.2d at 768; *Jeffreys,* 784 F. Supp. at 151. "Specific' jurisdiction refers to the situation in which the cause of action arises out of or relates to the defendant's contacts with the forum." *Beverly Hills Fan,* 21 F.3d at 1562 n.10; *see also Boone,* 724 A.2d at 1155.

In particular, subsection (c)(1) applies where a defendant "[t]ransacts any business or performs any character of work or service in the State" and that transaction or performance is related to the plaintiff's cause of action. Here, the cause of action is patent infringement:

Plaintiffs allege that Orchid India's filing of its memantine ANDA infringes Plaintiffs' '703

Patent. See Eli Lilly, 496 U.S. at 677 (holding that act of patent infringement under Hatch-Waxman Act is "submitting an ANDA . . . that is in error as to whether [development, manufacture, sale, etc. of the generic's proposed product] . . . violates the relevant patent").

However, neither Orchid India nor Orgenus have transacted any business or performed any work in Delaware relating to Orchid India's memantine ANDA filing.

The preparation and submission of Orchid India's memantine ANDA were performed by Orchid India in India and Orgenus in New Jersey and Maryland, not by either entity in Delaware. (D.I. 44 at 5; D.I. 45 ¶ 15; D.I. 46 ¶ 11; D.I. 89 at 5; D.I. 90 ¶¶ 12, 14) Although the major component by weight of Orchid India's proposed generic product is supplied by a Delaware company, as is the packaging, and while some of the clinical testing for the proposed product was conducted by a Delaware company, none of these products or services were both purchased in and manufactured or provided in Delaware. A meeting at DuPont "completely unrelated to the

causes of action asserted here" is also inadequate to establish (c)(1) specific jurisdiction, as in *Applied Biosystems*. 772 F. Supp. at 1466. These contacts are simply too insubstantial a basis for finding specific jurisdiction.

Plaintiffs claim that subsection (c)(3), requiring a showing that Defendant's actions in Delaware "[c]ause[d] tortious injury in the State," is satisfied as a result of certain mailings in Delaware that caused Plaintiffs tortious injury in Delaware. Organus mailed Orchid India's memantine ANDA from New Jersey to the FDA in Maryland. (D.I. 44 at 5; D.I. 46 ¶ 11; D.I. 89 at 5; D.I. 90 ¶ 12) Neither the filing nor the mailing occurred in Delaware. Similarly, it appears that Orchid India mailed notice of its ANDA and its accompanying Paragraph IV Certification<sup>7</sup> from India to Forest Labs, a Delaware corporation, in New York. (See D.I. 100 at 19; D.I. 102 Ex. 28). "The 'act' of mailing, for purposes of subsection (c)(3), is complete when the material is mailed." Sears, Roebuck & Co. v. Sears plc, 744 F. Supp. 1289, 1294 (D. Del. 1990) ("Sears I"). The mailing never came into Delaware and its sending was not an act in Delaware.

## 3. Dual Jurisdiction

Delaware courts have developed the concept of "dual jurisdiction" as they have grappled with application of Delaware's long-arm statute to situations in which jurisdiction is claimed to be based on the "stream of commerce." *See Power Integrations, Inc. v. BCD Semiconductor* 

<sup>&</sup>lt;sup>7</sup>A Paragraph IV Certification is something an ANDA filer must send to the patentholder when an ANDA filer asserts that the listed patent is invalid or would not be infringed by the generic company's manufacture and sale of its proposed drug; the filer must send the patentholder a "Paragraph IV Certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *Eli Lilly*, 496 U.S. at 677.

Corp., 547 F. Supp. 2d 365, 371-73 (D. Del. 2008). The "stream of commerce" theory is premised on the idea that a non-resident which places its product in the marketplace may, under certain circumstances, be found to have sufficient contacts for jurisdictional purposes with any state in which its product ends up. See id. at 371. Dual jurisdiction applies to patent infringement actions. See id. at 372-73.

In the context of dual jurisdiction, Delaware's courts have explained,

[O]ne must take great care not to overemphasize §§ 3104(c)(1) or (c)(4) under this analysis. It is not important that the indicia of activity under § 3104(c)(4) rise to a level of "general presence" as usually required. Instead, the enumerated activities in this section should be analyzed to determine whether there is an intent or purpose on the part of the manufacturer to serve the Delaware market with its product. Likewise, when analyzing § 3104(c)(1) it is not important that the manufacturer itself act in Delaware. Instead, if the intent or purpose on behalf of the manufacturer to serve the Delaware market results in the introduction of the product to this State and plaintiff's cause of action arises from injuries caused by that product, this section is satisfied.

Boone, 724 A.2d at 1157-58 (emphasis added).

Crucially, in order for dual jurisdiction to be present, at minimum a defendant's intent to serve the Delaware market must "result[] in the introduction of the product to this State." *Id.* at 1158. Consistent with the "longstanding principle that the jurisdiction of the Court depends upon the state of things at the time of the action brought," this must have occurred prior to the filing of the complaint. *Keene Corp. v. United States*, 508 U.S. 200, 207 (1993) (internal quotation marks omitted); *see also Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 570-71 (2004) ("It has long been the case that the jurisdiction of the court depends upon the state of things at the time of the action brought. This time-of-filing rule is hornbook law (quite literally) taught to

first-year law students in any basic course on federal civil procedure.") (internal quotation marks, footnote, and citation omitted); *Harlow v. Children's Hospital*, 432 F.3d 50, 61-62, 64-65 (1st Cir. 2005) ("[I]n analyzing specific jurisdiction, contacts must generally be limited to those before and surrounding the accrual of the cause of action. . . . [Thus,] in most cases, contacts coming into existence after the cause of action arose will not be relevant. . . . It is settled law that unrelated contacts which occurred after the cause of action arose, but before the suit was filed, may be considered for purposes of the general jurisdictional inquiry. . . . On the other hand, contacts after the filing of the complaint are not considered.").

Because Defendants' generic memantine product has not been introduced into Delaware – and, indeed, cannot be, unless and until Defendants receive FDA approval – the requirements for dual jurisdiction are not satisfied. Defendants' undisputed "intent . . . to serve the Delaware market" is simply not sufficient.

#### 4. Alter Ego And Agency Theories

Finally, Plaintiffs assert that personal jurisdiction over Orchid India and Orgenus is established because these two entities, along with Orchid Pharma, are "really three branches of the same business arm," working together to file ANDAs in the United States, facilitate the requisite FDA approval, and, ultimately, market and distribute generic products throughout the United States, including in Delaware. (D.I. 100 at 25-26; Tr. at 38-39, 49-50) Delaware law allows a court to find jurisdiction over a foreign parent corporation for the acts of its Delaware subsidiary on either alter ego or agency grounds. *See E.I duPont de Nemours and Co. v. Rhodia Fiber & Resin Intermediates, S.A.S.*, 197 F.R.D. 112, 122 (D. Del. 2000). Therefore, in applying

Delaware's long-arm statute, the Court "may consider the acts of an agent to the extent that those actions were directed and controlled by the principal." *Applied Biosystems*, 772 F. Supp. at 1465-66. However, under either the alter ego or agency theories, "the existence of a principal/agent relationship between two corporations does not obviate the necessity of satisfying the requirements of the Delaware long-arm statute." *Id.* at 1463.

Then-District Court Judge Roth described certain of the requirements for application of the alter ego and agency theories in *Applied Biosystems*:

... Under the alter ego or piercing the corporate veil doctrine, courts will ignore the corporate boundaries between parent and subsidiary if fraud or inequity is shown. The agency theory, by contrast, examines the degree of control which the parent exercises over the subsidiary....

If an agency relationship is found to exist, courts . . . will consider the parent corporation responsible for specific jurisdictional acts of the subsidiary.

Id.

Neither theory helps Plaintiffs here. With respect to the alter ego theory, the Plaintiffs have failed to show "fraud or inequity" in Orchid India's use of Orchid Pharma. As for agency theory, even assuming Orchid India exercises control over Orchid Pharma and Orgenus, these subsidiaries have insufficient contacts with Delaware. Even aggregating the contacts of all three entities does not result in sufficient contacts to permit the exercise of personal jurisdiction. See Wesley-Jessen Corp. v. Pilkington Visioncare, Inc., 863 F. Supp. 186, 190 (D. Del. 1993) (describing how jurisdiction was found lacking in Applied Biosystems because "even when the [] [subsidiary's] contacts were aggregated with the contacts of [the other defendants], there were insufficient contacts to permit the exercise of jurisdiction"); see also Applied Biosystems, 772

<sup>&</sup>lt;sup>8</sup>This is all the moreso if, as I recommend, Orchid Pharma is dismissed from this case, and its contacts with Delaware are not considered.

F. Supp. at 1469 (holding that act of incorporating an agent may be attributed to principal, although agent's status as Delaware corporation may not be so attributed).

#### B. Due Process

Because I find that neither Orchid India nor Orgenus have sufficient contacts with Delaware to satisfy the requirements of Delaware's long-arm statute, there is no need to reach the second-step constitutional question of whether exercise of jurisdiction here would violate the Defendants' due process rights. Plaintiffs have failed to meet their burden of establishing that this Court may exercise personal jurisdiction over Orchid India or Orgenus.

## C. Should The Court Dismiss Or Transfer?

Having found that this Court lacks personal jurisdiction over Orchid India and Orgenus does not, however, end the matter. Plaintiffs request that, rather than grant Defendants' motions to dismiss, the Court, instead, transfer these cases to the District of New Jersey. I agree that transfer is the appropriate disposition.

Two statutes potentially permit transfer in circumstances such as those presented here.

The first is 28 U.S.C. § 1406(a), entitled "Cure or waiver of defects," which provides:

The district court of a district in which is filed a case laying venue in the wrong division or district shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought.

The other potentially applicable statute is 28 U.S.C. § 1631; entitled "Transfer to cure want of jurisdiction," it provides:

Whenever a civil action is filed in a court . . . and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed . . . and the action . . . shall proceed as if it had been filed in . . . the court to which it is transferred on the date upon which it was actually filed in . . . the court from which it is transferred.

While Plaintiffs initially moved solely under Section 1406(a), in response to an inquiry from the Court<sup>9</sup> they requested transfer pursuant to both statutes. (D.I. 228) Defendants oppose transfer under both statutes. (D.I. 227) I find that both statutes are applicable here.<sup>10</sup>

<sup>&</sup>lt;sup>9</sup>"A court may *sua sponte* cure jurisdictional and venue defects by transferring a suit under the federal transfer statutes, 28 U.S.C. §§ 1406(a) and 1631, when it is in the interests of justice." *Trujillo v. Williams*, 465 F.3d 1210, 1222 (10th Cir. 2006); *see also Island Insteel Sys.*, *Inc. v. Waters*, 296 F.3d 200, 218 n.9 (3d Cir. 2002).

<sup>&</sup>lt;sup>10</sup>Although Section 1406 does not by its terms refer to jurisdiction, only venue, it has been construed as reaching challenges to subject matter and personal jurisdiction. See Goldlawr, Inc. v. Heiman, 369 U.S. 463, 466-67 (1962) ("The language of § 1406(a) is amply broad enough to authorize the transfer of cases, however wrong the plaintiff may have been in filing his case as to venue, whether the court in which it was filed had personal jurisdiction over the defendants or not. The section is thus in accord with the general purpose which has prompted many of the procedural changes of the past few years - that of removing whatever obstacles may impede an expeditious and orderly adjudication of cases and controversies on their merits."); Lafferty v. St. Riel, 495 F.3d 72, 83 (3d Cir. 2007) ("Goldlawr clarified that courts may use § 1406(a) to transfer cases involving defendants over whom they lack personal jurisdiction"); Ross v. Colo. Outward Bound Sch., Inc., 822 F.2d 1524, 1527 (10th Cir. 1987) ("[T]he language of § 1406(a) appears to apply only to those cases transferred for lack of proper venue, [but] the statute has been construed in an extraordinarily broad manner; courts have held that actions commenced in a district court where venue is proper but where personal jurisdiction is lacking may be transferred to a proper forum."). With respect to Section 1631, it is true, as Defendants point out, that former-District Court Judge Latchum wrote that this section "appears from its legislative history to apply only to cases in which the transferor court lacks subject matter jurisdiction," and not to a lack of personal jurisdiction. Nose v. Rementer, 610 F. Supp. 191, 192 n.1 (D. Del. 1985). But this was dicta - Judge Latchum's holding was to deny the requested transfer because the applicable statute of limitations had already run. See id. at 193. More importantly, regardless of how the legislative history appeared, the judicial construction – including by the Third Circuit – since the time Judge Latchum wrote has been to apply Section 1631 more broadly. See, e.g., Renner v. Lanard Toys Ltd., 33 F.3d 277, 284 (3d Cir. 1994) (remanding and observing in dicta that if plaintiffs continued to fail to show minimum contacts then transfer, pursuant to Sections

Sections 1406 and 1631 possess the same substantive requirements. Both require a showing by Plaintiffs that the action "could have been brought" in the transferee court at the time it was filed. Plaintiffs must also show that transfer would be "in the interest of justice." *See McCook Metals LLC* v. *Alcoa, Inc.*, 249 F.3d 330, 334 (4th Cir. 2001). Plaintiffs have met their burden.

The first prerequisite is relatively easily satisfied. "Defendants admit that personal jurisdiction is proper in New Jersey over Orgenus and Orchid India." (D.I. 227 at 2; *see also* D.I. 89 at 3 (Orgenus acknowledging that "both Orchid India and Orgenus are subject to suit in New Jersey"); Tr. at 29-30 (defense counsel conceding there would be jurisdiction over Orchid India and Orgenus in New Jersey).)

Defendants argue, however, that Civil Action 08-21 could not have been brought in New Jersey because the District Court there would not have jurisdiction over Orchid Pharma, a Delaware corporation. Given that jurisdictional discovery has revealed that Orchid Pharma is a "shell" company, and its presence is not necessary for Plaintiffs' pursuit of the instant litigation, Plaintiffs would now consent to dismiss Orchid Pharma. (D.I. 288 at 3; Tr. at 38, 50) I recommend that Orchid Pharma be dismissed. Given that all claims against the remaining Defendants challenging this Court's jurisdiction – Orchid India and Orgenus – could have been

<sup>1406</sup> or 1631, should be contemplated); *Mellon Bank (East) PSFS, N.A. v. DiVeronica Bros., Inc.*, 983 F.2d 551, 558 n.3 (3d Cir. 1993) (finding that district court lacked personal jurisdiction over defendant and remanding "for dismissal" but noting district court may also transfer pursuant to Section 1631); *see also Trujilo*, 465 F.3d at 1223 n.15 ("§ 1631 applies in cases where either subject matter jurisdiction or personal jurisdiction is lacking"); *Carpenter-Lenski v. Ramsey*, 210 F.3d 374, 2000 WL 287651, at \*2 (7th Cir. Mar. 14, 2000) ("Several courts . . . . have held that § 1631 applies in cases where either subject matter jurisdiction or personal jurisdiction is lacking.").

brought in New Jersey, the first prerequisite for transfer is satisfied.

The interests of justice also favor transfer as opposed to dismissal. This is, first, because Plaintiffs acted in good faith in filing suit in the District of Delaware. In doing so, Plaintiffs relied on a suggestion in Orchid India's 2004 Annual Statement that Orchid Pharma would be its regulatory agent for future FDA filings:

The US coordination work including acting as agent for filing of regulatory submissions with the US FDA was being carried out through a branch office in New Jersey, USA hitherto. In order to cater to the more demanding requirements of the US market, the Board felt that it would be more appropriate to have a separate entity formed in the US. Accordingly, your Company promoted Orchid Pharmaceuticals Inc. in Delaware state of USA as a 100% subsidiary company during the year under review.

(D.I. 63; D.I. 102 Ex. 6 at OCP00000368 (emphasis added)) The statement is ambiguous. While it implies that Orchid Delaware would henceforth serve as Orchid India's ANDA agent, it does not specifically say that. Still, at minimum, the implied meaning is a reasonable interpretation of the statement, as even Defendants concede. (Tr. at 64) Believing that Orchid Pharma, a Delaware corporation, was Orchid India's agent for ANDA purposes, Plaintiffs reasonably concluded that Orchid India was subject to suit here.

At the time they filed suit here in Delaware, Plaintiffs were not in possession of any definitive indication that Orchid Pharma was <u>not</u> Orchid India's agent for purposes of Orchid India's memantine ANDA. Defendants' Paragraph IV Certification letter did not identify any agent for Orchid India, so nothing about that letter contradicted Plaintiffs' reading of the Annual Statement. Plaintiff subsequently inquired of Defendants whether it could view Orchid India's memantine ANDA – from which it would have seen that Orgenus was Orchid India's agent – or whether Defendants would at least disclose the identity of Orchid India's agent, but Defendants

refused to provide the requested access or information. (D.I. 146 at 7; Tr. at 58)<sup>11</sup>

There were, as Defendants insist, publicly-available hints that Orgenus, and not Orchid Pharma, was Orchid India's agent on the memantine ANDA. For instance, in May 2007, Orgenus was listed as Orchid India's U.S. regulatory agent on a "suitability petition" for purposes of a proposed memantine product. (D.I. 46 Ex. 2; D.I. 134 at Ex. 4; D.I. 135 at Ex.14; *see also* D.I. 133 at 29 & n.9; Tr. at 52, 59-60.) However, this petition was related to a different ANDA than the one at issue in the instant case. (Tr. at 52) Plaintiffs analogize such evidence to "a needle in a haystack" that would have been difficult for them to identify. (*Id.*) I agree that, in the totality of circumstances, and most particularly the absence of any U.S. agent being identified in the Paragraph IV letter as well as Defendants' refusal to be more forthcoming about Orgenus' role in response to Plaintiff's pre-litigation inquiries, Plaintiffs' decision to file in Delaware was made in good faith.

Defendants also argue that some of the attorneys who represent Plaintiffs in the instant case have represented other pharmaceutical patent holders and, in other cases, have filed suits against Orgenus and Orchid India in New Jersey, not against Orchid Pharmaceuticals and not in Delaware. (D.I. 133 at 28) While it may be that some attorneys at some of the firms

<sup>&</sup>lt;sup>11</sup>Pursuant to 21 C.F.R. § 314.95(c)(7), if an ANDA applicant "does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant" must be included in the Paragraph IV Certification. Plaintiffs argue that Orchid India was required to identify its U.S. agent in the Paragraph IV Certification it sent to Plaintiffs. Defendants disagree, pointing out that Orchid India is registered to do business in New Jersey and has appointed CSC of West Trenton, New Jersey as its registered agent. (Tr. at 30-31) Whether or not Orchid India violated the letter or spirit of the regulatory requirement (or neither) is not a matter I need decide. Its failure to identify Orgenus as its agent until after this litigation was initiated, nonetheless, has implications for my recommendation that these cases be transferred rather than dismissed.

representing Plaintiffs have, in other cases for other clients involving other drugs at other times, known or believed that Orgenus was Orchid India's agent for ANDA purposes, there is no evidence that the very attorneys representing Plaintiffs at the time Plaintiffs filed the instant suit knew that Orgenus was Orchid India's agent on the memantine ANDA. (*See* Tr. at 38.) I am not persuaded that Plaintiffs' attorneys acted in bad faith, nor am I willing to attribute the knowledge or surmise of these attorneys to Plaintiffs.<sup>12</sup>

Defendants accuse Plaintiffs of taking "a calculated risk" Plaintiffs by filing suit in Delaware and not filing even a protective suit against them in New Jersey. (Tr. at 26) Even a calculated risk, however, is not necessary a bad faith decision. Moreover, Plaintiffs insist that

had Defendants revealed in a timely fashion that Orgenus was Orchid India's ANDA agent rather than Orchid Pharma, they would have – as they did with respect to six other defendants – filed a protective suit elsewhere, i.e., in New Jersey. (Tr. at 34, 37, 64) I find Plaintiffs' assertion credible.

A final reason the interests of justice favor transfer is the impact of dismissal might have on other defendants. Dismissal followed by initiation of a new suit in the District of New Jersey would come too late to give Plaintiffs the benefit of Hatch-Waxman's automatic thirty-month stay of FDA approval of Orchid India's memantine ANDA. It is possible that the lifting of the automatic stay as to Orchid India would lead to Orchid India's memantine ANDA being

<sup>&</sup>lt;sup>12</sup>The cases Defendants have cited do not involve the same type of circumstances I have found are presented here. *See Nichols v. G.D. Searle & Co.*, 991 F.2d 1195, 1200-02 (4th Cir. 1993) (upholding denial of transfer where plaintiff's attorney had made "obvious error," not an "erroneous guess with regard to an elusive fact"); *Cote v. Wadel*, 796 F.2d 981, 985 (7<sup>th</sup> Cir. 1986)(affirming dismissal where counsel made "elementary mistake by filing in wrong district).

approved prior to the memantine ANDAs filed by the other defendants in this action. If this were to occur, it would unfairly prejudice not just Plaintiffs, but also the other ANDA filers, all of whom (if necessary) identified their agents in Paragraph IV Certifications and all of whom would remain subject to the automatic stay. While I cannot assess the likelihood of this occurring, it is in the interests of justice to eliminate any possibility of it.

None of the cases cited by Defendants' require dismissal. In *Athletes Foot of Delaware*, *Inc. v. Ralph Libonati Co.*, 445 F. Supp. 35, 49 (D. Del. 1977), dismissal was chosen over transfer because – unlike here – "[t]here [wa]s no suggestion . . . that the plaintiffs in good faith or through excusable neglect, inadvertence, or mistake were led to believe that venue was proper in this district." Similarly, in *Nichols*, 991 F.2d at 1200-02, the Fourth Circuit upheld denial of a transfer motion where the plaintiff's attorney had made an "obvious error" in choosing where to file the action. *See also Deleski v. Raymark Indus., Inc.*, 819 F.2d 377 (3d Cir. 1987) (affirming district court's denial of transfer because plaintiff's counsel should have known the chosen forum was improper); *see generally Trujillo*, 465 F.3d at 1223 (noting that factor warranting transfer as opposed to dismissal is "that the original action was filed in good faith rather than after plaintiff either realized or should have realized that the forum in which he or she filed was improper") (internal quotation marks omitted).

Therefore, pursuant to both Sections 1406 and 1631, I recommend that Plaintiffs' motions to transfer their claims against Orchid India and Orgenus to the District of New Jersey be granted. It follows that, notwithstanding the lack of personal jurisdiction this Court has over Defendants, I recommend denial of Defendants' motion to dismiss.

**RECOMMENDED DISPOSITION** 

Based on the foregoing, I recommend that the Court GRANT Plaintiffs' motions to

transfer the causes of action as to Orchid India and Orgenus. (D.I. 99; D.I. 153) I further

recommend that Defendants' motions to dismiss (D.I. 43; D.I. 87) be DISMISSED AS MOOT.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R.

Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections

within ten (10) days after being served with a copy of this Report and Recommendation. Fed. R.

Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the

right to de novo review in the district court. See Henderson v. Carlson, 812 F.2d 874, 878-79

(3d Cir. 1987); Sincavage v. Barnhart, 171 Fed. Appx. 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order In Non-Pro Se Matters For

Objections Filed Under Fed. R. Civ. P. 72, dated April 7, 2008, a copy of which is available on

the Court's website, www.ded.uscourts.gov/StandingOrdersMain.htm.

Dated: March 9, 2009

Honorable Leonard P. Stark

UNITED STATES MAGISTRATE JUDGE

29